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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,170	02/04/2002	Paul Douglas Clarke	TPP 31435	4789

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Washington, DC 20036

EXAMINER

COE, SUSAN D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 03/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

8M

## Office Action Summary

Application No.

10/031,170

Applicant(s)

CLARKE, PAUL DOUGLAS

Examiner

Susan Coe

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on December 3 and 29, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 36-55 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 36-55 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 3, 2003 has been entered.
2. Claims 36-55 are currently pending.
3. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.

***Claim Rejections - 35 USC § 102***

4. Claims 36-40 and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,298,250 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach adding p-methane-3,8-diol (PMD) in the amount of 0.25% to 5% by weight of the total composition. However, the reference does teach adding PMD in these amounts. Claim 9 of this reference states that compounds A and B (trans and cis isomers of PMD) are present at at least 57% by weight of the total active composition. The active composition is then formulated in the form of an aerosol or a lotion where the active composition is present at at least 5% by weight of the total repellent composition (see claim 12). Thus, in the total repellent composition, there can be about 2.5% PMD. This amount meets the limitation of applicant's claims.

5. Claims 36-40 and 44-46 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,698,209 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach adding PMD in the amount of 0.25% to 5% by weight of the total composition. However, the reference does teach adding PMD in these amounts. The reference teaches a composition that contains PMD and a pyrethroid to form an active composition. This active composition can be included in a pharmaceutical composition from 0.1 to 70% by weight of the total pharmaceutical composition (see column 3, lines 23-31). The PMD and pyrethroid are present from 1:1 to 50:1, PMD to pyrethroid (see claim 1). Thus, US '209 teaches adding PMD in a wide variety of amounts that meets the limitations of applicant's claims.

***Claim Rejections - 35 USC § 103***

6. Claims 41-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,298,250 for the reasons set forth in the previous Office action.

Applicant argues against this rejection in combination with the argument against the 102(b) rejection over this reference. Therefore, the rejection is considered valid for the reasons stated above and in the previous Office action.

7. Claims 41-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,698,209 for the reasons set forth in the previous Office action.

Applicant argues against this rejection in combination with the argument against the 102(b) rejection over this reference. Therefore, the rejection is considered valid for the reasons stated above and in the previous Office action.

8. Claims 36-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shahi et al. (Current Science (Bangalore) (March 1999), vol. 76, no. 6, pp. 836-839) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach adding PMD in the amount of 0.25% to 5% by weight of the total composition. However, the reference does teach using oil from *E. citriodora* which would contain PMD. The composition is a topical anti-fungal composition which contains up to 5% of the plant oil (see page 838, second column, fifth paragraph). An additional embodiment contains 1% of the plant oil. While it is not readily apparent how much PMD is present in the oil composition, it seems reasonable to assume that it is present in amounts that would meet the limitations of applicant's claims. In addition, the person of skill in the art would be motivated to modify the amount of plant oil used and the concentration of plant oil used in the anti-fungal composition in order to achieve the best anti-fungal results. Therefore, variations in the amount of oil would also yield compositions containing applicant's claimed amount of PMD.

9. Claims 36-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Muanza et al. (Int. J. Pharmacog (1994), vol. 32, no. 4, pp. 337-345) for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach adding PMD in the amount of 0.25% to 5% by weight of the total composition. However, the reference does teach using oil from *E. citriodora* which would contain PMD. It is not readily apparent how much PMD is present in the oil composition; however, the person of skill in the art would be motivated to modify the amount of plant oil used and the concentration of plant oil used in the anti-fungal composition in order to achieve the best anti-fungal results. Therefore, variations in the amount of oil would yield compositions containing applicant's claimed amount of PMD.

10. No claims are allowed.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period

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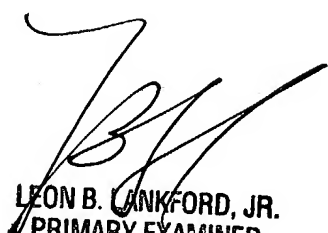
will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner  
March 3, 2004



LEON B. LINKFORD, JR.  
PRIMARY EXAMINER